

AMENDED IN ASSEMBLY JANUARY 13, 2012

AMENDED IN ASSEMBLY JANUARY 4, 2012

AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 510

Introduced by Assembly Member Bonnie Lowenthal

February 15, 2011

An act to amend Sections 115111, *115112*, and 115113 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 510, as amended, Bonnie Lowenthal. Radiation control: health facilities and clinics: records.

Under existing law, the State Department of Public Health licenses and regulates health facilities and clinics, as defined. Under existing law, the Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law, the department is authorized to require registration and inspection of sources of ionizing radiation, as defined. Existing law, commencing July 1, 2012, requires that a facility using a computed tomography (CT) X-ray system record the dose of radiation on every CT study produced. Existing law requires that the displayed dose of radiation be verified annually by a medical physicist to ensure the accuracy of the displayed dose unless the facility is accredited. Violations of these provisions are a crime.

This bill would exempt specified CT studies from being required to record the dose. This bill would delete the exemption for accredited facilities and ~~authorize accredited facilities~~ would authorize a facility

that has an accredited machine to elect not to annually verify the displayed dose of radiation, as specified. Because accredited facilities could now be subject to these provisions, and because a violation of these provisions is a crime, the bill would impose a state-mandated local program by expanding the scope of a crime. The bill also would require the dose to be verified for the facility's standard adult brain, adult abdomen, and pediatric brain protocols.

Existing law, commencing July 1, 2013, requires facilities that furnish CT X-ray services to be accredited by an approved organization, as specified.

This bill would not require the facilities to be accredited, but instead would require the CT X-ray systems to be accredited by an approved organization, as specified.

Existing law, commencing July 1, 2012, requires a facility to report the discovery of certain information about an event in which the administration of radiation results in prescribed occurrences, *including the CT X-ray irradiation of an area of the body other than that intended*, within 5 business days of the discovery of the event, to the department and the patient's referring physician.

This bill would require instead a facility to report a CT X-ray irradiation image that does not include the intended anatomic area. This bill would provide that reporting is not required if adjacent body parts are irradiated during the same treatment, unless specified. This bill would instead require that this report be made within 10 business days of the discovery of the event.

The bill would also make technical and clarifying changes.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 115111 of the Health and Safety Code
- 2 is amended to read:
- 3 115111. (a) Commencing July 1, 2012, subject to subdivision
- 4 (e), a person that uses a computed tomography (CT) X-ray system

1 ~~dedicated to only diagnostic~~ *for human use* shall record the dose
2 of radiation on every CT study produced during a CT examination
3 ~~on a system. CT studies used for therapeutic radiation treatment~~
4 *planning or image guidance for interventional radiologic*
5 *procedures shall not be required to record the dose.*

6 (b) The facility conducting the study shall electronically send
7 each CT study and protocol page that lists the technical factors
8 and dose of radiation to the electronic picture archiving and
9 communications system.

10 (c) (1) The displayed dose shall be verified annually by a
11 medical physicist for the facility's standard adult brain, adult
12 abdomen, and pediatric brain protocols, to ensure the displayed
13 doses are within 20 percent of the true measured dose measured
14 in accordance with subdivision (f).

15 (2) A facility that *has a machine that* is accredited may elect
16 not to perform the verification described in paragraph (1).

17 (d) Subject to subdivision (e), the radiology report of a CT study
18 shall include the dose of radiation by either recording the dose
19 within the patient's radiology report or attaching the protocol page
20 that includes the dose of radiation to the radiology report.

21 (e) The requirements of this section shall be limited to CT
22 systems capable of calculating and displaying the dose.

23 (f) For the purposes of this section, dose of radiation shall be
24 defined as one of the following:

25 (1) The computed tomography index volume (CTDI vol) and
26 dose length product (DLP), as defined by the International
27 Electrotechnical Commission (IEC) and recognized by the federal
28 Food and Drug Administration (FDA).

29 (2) The dose unit as recommended by the American Association
30 of Physicists in Medicine.

31 *SEC. 2. Section 115112 of the Health and Safety Code is*
32 *amended to read:*

33 115112. Commencing July 1, 2013, ~~facilities that furnish CT~~
34 ~~X-ray services~~ *CT X-ray systems* shall be accredited by an
35 organization that is approved by the federal Centers for Medicare
36 and Medicaid Services, an accrediting agency approved by the
37 Medical Board of California, or the State Department of Public
38 Health.

1 ~~SEC. 2.~~

2 SEC. 3. Section 115113 of the Health and Safety Code, as
3 amended by Section 1 of Chapter 139 of the Statutes of 2011, is
4 amended to read:

5 115113. (a) Except for an event that results from patient
6 movement or interference, a facility shall report to the department
7 an event in which the administration of radiation results in any of
8 the following:

9 (1) Repeating of a CT examination, unless otherwise ordered
10 by a physician or a radiologist, if *one of* the following dose values
11 are exceeded:

12 (A) 0.05 Sv (5 rem) effective dose.

13 (B) 0.5 Sv (50 rem) to an organ or tissue.

14 (C) 0.5 Sv (50 rem) shallow dose to the skin.

15 (2) ~~A CT X-ray irradiation of an area of the body other than that~~
16 ~~intended image that does not include the intended anatomic area~~
17 by the ordering physician or a radiologist if ~~at least~~ one of the
18 following dose values are exceeded:

19 (A) 0.05 Sv (5 rem) effective dose.

20 (B) 0.5 Sv (50 rem) to an organ or tissue.

21 (C) 0.5 Sv (50 rem) shallow dose to the skin.

22 (3) CT or therapeutic exposure that results in unanticipated
23 permanent functional damage to an organ or a physiological
24 system, hair loss, or erythema, as determined by a qualified
25 physician.

26 (4) A CT or therapeutic dose to an embryo or fetus that is greater
27 than 50 mSv (5 rem) dose, that is a result of radiation to a known
28 pregnant individual unless the dose to the embryo or fetus was
29 specifically approved, in advance, by a qualified physician.

30 (5) Therapeutic ionizing irradiation of the wrong individual or
31 the wrong ~~nonoverlapping~~ treatment site. *Reporting is not required*
32 *if adjacent body parts are irradiated during the same treatment,*
33 *unless they exceed the values in paragraph (6) of this subdivision.*

34 (6) The total dose from therapeutic ionizing radiation delivered
35 differs from the prescribed dose by 20 percent or more. A report
36 shall not be required pursuant to this paragraph in any instance
37 where the dose administered exceeds 20 percent of the amount
38 prescribed in a situation where the radiation was utilized for
39 palliative care for the specific patient. The radiation oncologist
40 shall notify the referring physician that the dose was exceeded.

1 (b) The facility shall, no later than 10 business days after
2 discovery of an event described in subdivision (a), provide
3 notification of the event to the department and the referring
4 physician of the person subject to the event and shall, no later than
5 15 business days after discovery of an event described in
6 subdivision (a) provide written notification to the person who is
7 subject to the event.

8 (c) This section shall become inoperative on the effective date
9 of the act that added this subdivision, and shall remain inoperative
10 until July 1, 2012.

11 ~~SEC. 3.~~

12 *SEC. 4.* No reimbursement is required by this act pursuant to
13 Section 6 of Article XIII B of the California Constitution because
14 the only costs that may be incurred by a local agency or school
15 district will be incurred because this act creates a new crime or
16 infraction, eliminates a crime or infraction, or changes the penalty
17 for a crime or infraction, within the meaning of Section 17556 of
18 the Government Code, or changes the definition of a crime within
19 the meaning of Section 6 of Article XIII B of the California
20 Constitution.